

REMARKS

Claims 1, 4-10, 16-23, 28 and 29 are pending. No new matter has been added by way of the present amendment. For instance, claim 1 has been amended to remove the recitation of nucleotide sequences of SEQ ID NO: 1, SEQ ID NO: 2, and a nucleotide sequence obtained from a polynucleotide which is amplified from a nucleic acid obtained from soybean with a combination of a PCR primer of SEQ ID NO: 9 and a PCR primer of SEQ ID NO: 10. Also, the nucleotide sequence of (g) (previously (j)), has been amended to be obtained from beet. Further, the nucleotide sequence of (h) (previously (k)), has been amended to be obtained from mustard or rapeseed. Support for these limitations may be found at, for example, page 3, lines 14-17, Example 3, and Example 5 of the substitute specification. Additionally, claims 2, 3 and 30 have been cancelled. Accordingly, no new matter has been added.

In view of the present submission, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 1-5, 8-10, 16-23 and 28-30 under 35 U.S.C. § 112, first paragraph for the reasons recited at pages 2-8 of the outstanding Office Action. Applicants respectfully traverse each of these rejections.

The Examiner has presented various "written description" and "enablement" rejections, which will be addressed separately.

1. Written Description

The Examiner has rejected claims 1-5, 8-10, 16-23 and 18-30 under 35 U.S.C. § 112, first paragraph, for allegedly failing to satisfy the written description requirement. Applicants traverse.

1.1 SEQ ID NOS: 1 and 7

At pages 3-4 of the outstanding Office Action, the Examiner asserts that claims directed to isolated nucleic acids encoding SEQ ID NOS: 1 or 7 lack sufficient written description. Applicants respectfully disagree.

First, SEQ ID NO: 1 is no longer recited in the present claims. Thus, this aspect of the Examiner's rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Second, concerning SEQ ID NO: 7, Applicants submit that this sequence is specifically disclosed in the present specification, for instance, refer to the originally filed Sequence Listing. However, the Examiner appears to believe that Applicants are attempting to claim a nucleic acid sequence wherein only an "incomplete" amino acid sequence has been disclosed. The Examiner relies on the case law of *In re Wallach*, 71 USPQ2d 1939 (Fed. Cir. 2004). Applicants submit that the present facts are distinct from those presented in *Wallach*.

In *Wallach*, there was disclosed two specific proteins isolated from human urine that selectively inhibit the cytotoxic effect of tumor necrosis factor ("TNF"). These proteins were named TNF binding proteins I & II ("TBP-I" and "TBP-II"). After obtaining a partial amino acid sequence of the N-terminal portion of TBP-II and determining that the complete protein has a molecular weight of about 30 kDa when measured by SDS-PAGE under reducing conditions, the

inventors filed a patent application including claims directed to proteins having that molecular weight and a partial sequence and having the ability to inhibit the cytotoxic effect of TNF. Claims were also included to isolated DNA molecules that encode the claimed (complete) proteins.

The U.S.P.T.O. issued a restriction requirement and inventors filed divisional applications. The claims at issue in *Wallach* were those directed to the DNA, and were rejected under § 112, first paragraph, written description. The claim, in particular, at issue in *Wallach*, is as follows:

11. An isolated DNA molecule comprising a contiguous nucleotide sequence coding for a protein consisting of naturally occurring human Tumor Necrosis Factor (TNF) Binding Protein II, herein designated TBP-II, said TBP-II including the amino acid sequence: Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr in the portion of the protein sequenced by N-terminal sequence analysis, said protein having the ability to inhibit the cytotoxic effect of TNF, wherein said naturally occurring TBP-II protein is the same as that protein having the ability to inhibit the cytotoxic effect of TNF which, after being purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized TNF, elutes from a reversed-phase high pressure liquid chromatography column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 30 kDa when measured by SDS-PAGE under reducing conditions.

The Federal Circuit found insufficient written description for claim 11 in *Wallach* above. Importantly, in *Wallach* there was 95% of the amino acid sequence of the protein missing from the description. Also, no DNA sequences were disclosed, and as noted, no full-length protein sequences were provided. Based upon these facts, the Federal Circuit found for lack of written description for the above claim 11. *Wallach*, at 1942-43.

However, the present facts differ from *Wallach*. In the present application, at least two complete amino acid sequences of raffinose synthases (SEQ ID NO: 3 and SEQ ID NO: 5) and

two complete nucleotide sequences of raffinose synthase genes (SEQ ID NO: 4 and SEQ ID NO: 6) are specifically disclosed.

SEQ ID NO: 7 of the present invention is an amino acid sequence consisting of 572 amino acids (corresponding to about 70% of the full length amino acid sequence of raffinose synthase). Further, this amino acid sequence has a homology of about 98% to the amino acid sequence from amino acid 206 to amino acid 777 of SEQ ID NO: 5. Additionally, the nucleotide sequence of SEQ ID NO: 8, also disclosed, encodes the amino acid sequence of SEQ ID NO: 7. The specification also discloses the method for obtaining the full-length nucleotide sequence based upon the approximately 70% sequence. For instance, the Examiner is respectfully requested to refer to the present substitute specification at page 17, line 14 to page 21, line 9, and Example 7).

In view of the above, Applicants submit that the case of *Wallach* is distinguished. Further, based upon the originally filed specification, those of skill in the art would understand that Applicants were in possession of an isolated nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 7 at the time of filing. Therefore, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

1.2 SEQ ID NO: 3

The Examiner has also asserted at page 4 of the outstanding Office Action that claims directed to isolated nucleic acids encoding the amino acid sequence of SEQ ID NO: 3 have

insufficient written description since "Applicant has failed to adequately establish a structural-functional relationship." Applicants respectfully disagree with the Examiner.

The Examiner asserts that a claimed invention as a whole may not be adequately described wherein an invention is described solely in terms of a method of its making coupled with its function where there is no described or art-recognized correlation or relationship between the structure of the invention and its function. However, in the present instance, Applicants are specifically claiming a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 3. SEQ ID NO: 3 represents a complete amino acid sequence of a raffinose synthase. Thus, a large amount of structure, in particular, SEQ ID NO: 3, is disclosed and claimed.

Further, it is unnecessary to disclose the corresponding nucleic acid sequences which could encode SEQ ID NO: 3. The Federal Circuit found that there is no requirement for a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed, given the fact that it is a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it. *Wallach*, at 1942.

Thus, whether or not Applicants have failed to show a structure/function relationship between the amino acid sequence of SEQ ID NO: 3 and the function recited, for instance in the preamble of claim 1, is irrelevant. Such a rejection would only be relevant if Applicants were simply attempting to claim a nucleic acid by way of what its encoded amino acid does, rather

than what it is. In view of this misunderstanding, Applicants respectfully request that the Examiner withdraw this rejection.

1.3 Nucleotide Sequences Obtained by PCR Amplification

The Examiner asserts at pages 4-5 of the outstanding Office Action that claims directed to isolated nucleic acids having a nucleotide sequence obtained by PCR amplification from other plants and which hybridize to an exemplified nucleic acid have insufficient written description. In particular, the Examiner asserts that there is an insufficiently described genus of isolated nucleic acids encoding raffinose synthase. The Examiner relies upon the case law of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Applicants respectfully traverse and submit that this rejection is improper.

Applicants direct the Examiner's attention to the fact that claim 1, limitation (i) has been cancelled. Also, limitations (g) and (h) (formerly limitations (j) and (k)) relate to nucleotide sequences which are obtained via PCR amplification. This should not be a barrier to patentability since Applicants have specifically recited the source in limitation (g) as beet and in limitation (k) as mustard or rapeseed. Further, the specific primers and hybridization conditions are recited for each limitation.

Based upon this claim language, Applicants respectfully submit that those of ordinary skill in the art would understand that possession of amplification products from each of these specifically disclosed plants, and possession of conditions for amplification necessarily include possession of the presently claimed subject matter. Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

2. Enablement

The Examiner has rejected claims 1-5, 8-10, 16-23 and 28-30 under 35 U.S.C. § 112, first paragraph, asserting that the specification, while being enabling for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 5, plants transformed therewith and methods of using such isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids encoding raffinose synthase. Applicants respectfully traverse.

Based upon the present claims, Applicants respectfully submit that the present claims are fully enabled. That is, based upon the level of skill in the art, those of skill would be able to make and use the presently claimed subject matter without undue burden. Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Allowable Subject Matter

The Examiner has indicated at page 8 of the outstanding Office Action that claims 6 and 7 are objected to as simply being dependent upon a rejected base claim, but would be allowable if rewritten into independent format. Applicants point out that these claims are already independent claims. However, in view of the above arguments, Applicants respectfully submit that all pending claims are in condition for allowance. The Examiner is therefore requested to withdraw all rejections and allow the currently pending claims.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie (Reg. 42,874) at the telephone number of the undersigned below.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition

for an extension of three (3) months to September 1, 2005, in which to file a reply to the Office Action. The required fee is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: August 31, 2005

Respectfully submitted,

By 

John W. Bailey

Registration No.: 32,881

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Rd.

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant